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EXAMINER
KRUPENIK

ART USE PAPER NUMBER
181 10

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This application has been examined Responsive to communication filed on 10/23/89 This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. Notice of References Cited by Examiner, PTO-892.
2. Notice re Patent Drawing, PTO-948.
3. Notice of Art Cited by Applicant, PTO-1449.
4. Notice of Informal Patent Application, Form PTO-152.
5. Information on How to Effect Drawing Changes, PTO-1474.
6.

Part II SUMMARY OF ACTION

1. Claims 1-30 are pending in the application.

Of the above, claims 23-30 are withdrawn from consideration.

2. Claims _____ have been cancelled.

3. Claims _____ are allowed.

4. Claims 1-23 are rejected.

5. Claims _____ are objected to.

6. Claims _____ are subject to restriction or election requirement.

7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. Formal drawings are required in response to this Office action.

9. The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are acceptable. not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been approved by the examiner. disapproved by the examiner (see explanation).

11. The proposed drawing correction, filed on _____, has been approved. disapproved (see explanation).

12. Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on _____

13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. Other

EXAMINER'S ACTION

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-22, drawn to a method of DNA sequencing, classified in Class 435, subclass 6, for example.

II. Claims 23-30, drawn to systems for electrophoretic analysis of DNA, classified in Class 422, subclass 68 or Class 435, subclass 287.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP 806.05(e)). In this case, the process as claimed can be practiced by hand and the apparatus can be used to practice another and materially different process such as peptide sequencing.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Meuth on 12/4/89 a

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provisional election was made with traverse to prosecute the invention of I, claim 1-22. Affirmation of this election must be made by applicant in responding to this Office action. Claims 23-30 have been withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor if at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

The application should be reviewed for errors. Errors appear in the spelling of "may be" on page 11, line 17 and "hydroxide" on page 19, line 29.

Figure 1 is objected to for the following reason: there appears to be a mistake in the DNA code in (a) in the top upper left 5' to 3' sequence, the DNA number 11 from the 5' end.

On page 10, line 38 and in the abstract, the current status of abandoned application S.N. 709,579 should be provided.

Corrections are required.

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Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited to the particular covalently bond dye-fragment attachments shown to be useful, i.e., each of the 4 dye attachment are claimed wherein the emission spectrum of each dye is separately resolved adsorption maxima and/or emission maxima.

Applicants' claims are directed to colored or fluorescent labels. Applicants have not disclosed in the claims the method which the primer oligonucleotide is bonded to the dye or label. Applicants have disclosed on page 10 that the coupling of the tags is described in copending S.N. 565,010. This application should be updated. Applicants' claims are enabled only for such methods of coupling.

See MPEP 706.03(n) and 706.03(z).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to provide an enabling disclosure.

The invention is enabled for a selected set of at least four fluophores with different emission spectra which are tagged to the four different nucleotides. Nothing less than 4 tags with four highly resolvable extinction coefficients are enabled in the process set forth in the invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the objection to the specification.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

"A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same

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person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicants are advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1-6 rejected under 35 U.S.C. 103 as being unpatentable over Kaplan et al and applicants' disclosure of the method of Maxim and Gilbert described on page 3, in view of Khanna et al .

Kaplan et al teach the separation of samples by gel electrophoresis and detection of separated material by ultraviolet transmitting material, column 3, lines 5-10. The disclosure recites the Maxim and Gilbert method in which radiolabeled oligonucleotide samples are separated by gel electrophoresis for the purpose of sequencing DNA. Khanna et al disclose that fluorescent dye molecules may be attached to oligonucleotides.

It would be obvious for one skilled in the art to substitute various dyes having different emission spectra for radioactive phosphate in the method of separating DNA fragments by gel electrophoresis of Maxim and Gilbert and Kaplan for the purpose of utilizing non-hazardous material in the laboratory.

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Thus, the claimed invention as a whole was clearly prima facie obvious over the references, in the absence of sufficient, clear and convincing evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Karen Krupen, Ph.D., whose telephone number is (703) 557-6641. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 557-0664.

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12/4/89

Christine M. Moore
CHRISTINE M. MOORE
PRIMARY EXAMINER
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